

press release

Health Canada approves RYBELSUS® (semaglutide tablets) the first and only GLP-1 analogue in a pill for the treatment of adults with type 2 diabetes

RYBELSUS® offers convenience to support diabetes management along with diet and exercise for adults¹

MISSISSAUGA, ON – April 9, 2020 - Health Canada has approved RYBELSUS® (semaglutide tablets) as a treatment option to improve glycemic control in adults with type 2 diabetes mellitus, along with diet and exercise.¹ RYBELSUS® is the first and only glucagon-like peptide-1 (GLP-1) analogue available in a tablet and is indicated as a monotherapy when metformin is considered inappropriate due to intolerance or contraindications. RYBELSUS® can be used in combination with other medicinal products for the treatment of type 2 diabetes in adults.¹

RYBELSUS® will be available in pharmacies across Canada beginning April 27, 2020.

“Being diagnosed with diabetes and managing a chronic disease can be overwhelming. Providing patients effective and convenient choices to manage their condition is essential,” says Vicky Chan, Vice President, Clinical Development, Medical and Regulatory Affairs, Novo Nordisk Canada Inc. “RYBELSUS® offers Canadians living with type 2 diabetes an oral medication option, which was previously only available as an injection. At Novo Nordisk Canada, we are continuously focused on creating new innovative treatment options to support the needs of Canadians living with type 2 diabetes,” said Chan.

The efficacy and safety of RYBELSUS® has been evaluated in seven global randomised controlled phase 3a trials.¹ In six trials, the primary objective was the assessment of the glycemic efficacy; in one trial, the primary objective was the assessment of cardiovascular outcomes. **Glycemic efficacy** - the phase 3a trials comprised 8,336 randomised patients with type 2 diabetes (4,915 treated with RYBELSUS® including 1,162 patients with moderate renal impairment). The results of the trials demonstrated a superior A1C reduction compared with placebo.¹ Across the PIONEER clinical trial program, RYBELSUS® demonstrated a safe and well-tolerated profile, with the most common adverse event being mild to moderate nausea, diarrhea, and vomiting which

diminished over time.¹ In an open label, active-controlled trial, RYBELSUS® demonstrated statistically significant reductions in HbA1c vs sitagliptin, empagliflozin and liraglutide and with up to 4.3 kg weight reduction after 52 weeks.¹ **Cardiovascular outcome trial** - RYBELSUS® did not result in any unacceptable increase in major adverse cardiac events (MACE) compared to placebo in patients with type 2 diabetes mellitus at high risk of cardiovascular events.¹

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 42,700 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.ca, [Twitter](#), or [YouTube](#).

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¹ RYBELSUS® (semaglutide tablets), Novo Nordisk Canada Inc., [Product Monograph](#), March 30, 2020